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10/825,043

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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

12/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|-------------------------------------|--|
| Office Action Summary | Application No. 10/825,043 | Applicant(s) RIEHL ET AL. | |
| | Examiner CHRISTINE D. HOPKINS | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) 16-35, 42-58 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 36, 37 and 59-68 is/are rejected.
- 7) ☒ Claim(s) 10-15 and 38-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>30 July 09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 30 July 2009.

Claims 1-69 are now pending. The Examiner acknowledges the amendments to claim 36.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-7 and 59-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Ruohonen et al. (U.S. Patent No. 6,849,040). Ruohonen et al. (hereinafter Ruohonen) disclose a method and apparatus for determining the effects of magnetic stimulation on the brain. Regarding claims 1-3, 5, 6, 59-62 and 64, Ruohonen teaches a system comprising: a magnetic stimulation coil **1** (capable of functioning as a TMS coil) having two treatment faces (opposing ends of the coil) for treating a patient; a pulse generating device **8** that applies pulses to the coil; a sensor (such as those arranged on a pair of eyeglasses as taught at col. 5, lines 1-2) disposed between the coil and a position at which pulses are applied, the sensor detecting proximity of the coil to the position; and signal processing circuitry **3** having display **4** (col. 4, lines 43-60) that processes outputs of the sensor to provide indication of coil placement with respect

to the position of the sensor during pulsing (col. 3, lines 66-67 - col. 4, lines 1-30).

Regarding claims 4 and 63, since signal processing circuitry **3** processes output from the sensors arranged on the eyeglasses of the patient, it is capable of determining if the TMS coil has a valid contact with the patient at a particular position.

With respect to claims 7, 65 and 66, the display presents a “pressure map” of the patient’s head as the operator controls the coil into an optimal position, thus capable of displaying “proper contact.”

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9 and 68 rejected under 35 U.S.C. 103(a) as being unpatentable over Ruohonen et al. (U.S. Patent No. 6,849,040). Ruohonen discloses the invention as claimed, to include a substrate disposed between a coil and a position of a patient and at least one sensor disposed on the substrate to detect proximity of the coil to a position using a magnetic field; however Ruohonen does not disclose expressly that the sensor is disposed in a flexible substrate. Instead, Ruohonen indicates that the sensor is arranged on a pair of eyeglasses (col. 5, lines 1-2), which allow conformation to the patient’s head. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a flexible substrate

because Applicant has not disclosed that a flexible substrate provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Ruohonen's stimulation system and applicant's invention, to perform equally well with either the substrate taught by Ruohonen or the claimed flexible substrate because both would perform the same function of enabling conformation to the skin of a patient. Therefore, at the time of the invention it would have been prima facie obvious to modify Ruohonen to obtain the invention as specified in claims 9 and 68 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Ruohonen.

6. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boveja (U.S. Pub. No. 2001/0002441). Boveja discloses the invention as claimed, to include a substrate disposed between a coil and a position of a patient and at least one sensor disposed on the substrate to detect proximity of the coil to a position using a magnetic field; however Boveja does not disclose expressly that the sensor is disposed in a flexible substrate. Instead, Boveja indicates that the sensor or sensing unit contained in the coil is taped firmly to the skin for efficient energy transfer to occur [0051]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a flexible substrate because Applicant has not disclosed that a flexible substrate provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Boveja's stimulation system and applicant's invention, to perform equally well with either the substrate taught by Boveja or the claimed flexible substrate because both

would perform the same function of enabling conformation to the skin of a patient.

Therefore, at the time of the invention it would have been prima facie obvious to modify Boveja to obtain the invention as specified in claim 36 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Boveja.

7. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boveja (U.S. Pub. No. 2001/0002441) in view of Grove et al. (U.S. Pub. No. 2004/0167592). Boveja discloses the invention as claimed, see rejection supra; however Boveja does not disclose a membrane switch. Grove et al. (hereinafter Grove) teaches an apparatus which employs a therapeutic energy source and one or more switches placed in contact with a person's skin. Regarding claim 37, Grove discloses that a contact sensor, as similarly taught by Boveja, may be a type of membrane switch such that when the apparatus is pressed against the skin, the membrane switch closes, indicating the initiation of pulsing therapy [0016]. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have incorporated membrane switches as disclosed by Grove into a therapeutic pulsing apparatus as taught by Boveja for indicating contact with a patient's skin and subsequently initiating therapy.

Moreover, the combination of Boveja in view of Grove discloses the invention as claimed, see rejection supra; however the combination does not disclose expressly that the membrane switch comprises respective conducting films separated by a dielectric layer. Instead, Boveja in view of Grove discloses that a contact sensor may be a type of membrane switch such that when the apparatus is pressed against the skin, the

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membrane switch closes, indicating the initiation of pulsing therapy [0016]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a membrane switch comprising respective conducting films separated by a dielectric layer because Applicant has not disclosed that such a membrane switch provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Boveja in view of Grove's stimulation system and applicant's invention, to perform equally well with either the membrane switches taught by Boveja in view of Grove or the claimed membrane switch comprising respective conducting films separated by a dielectric layer because both would perform the same function of sensing positioning and contact with the skin of the patient. Therefore, at the time of the invention it would have been prima facie obvious to modify Boveja in view of Grove to obtain the invention as specified in claims 10 and 37 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Boveja in view of Grove.

8. Claims 8 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruohonen et al. (U.S. Patent No. 6,849,040) in view of Boveja (U.S. Pub. No. 2001/0002441). Ruohonen discloses the invention as claimed, see rejection supra; however Ruohonen fails to disclose a sound generator indicating that the coil is properly positioned. Boveja teaches an apparatus and method for neurological therapy. Regarding claim 67, Boveja teaches that if the proximity distance drops off such that the coil is not within a therapeutic range, an alarm indicates failure noting improper contact.

Ruohonen likewise discloses a display and software which provide visualization of the coil as well as interactively requesting the operator to move the coil so that the desired dose is achieved (col. 4, lines 48-58). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have incorporated a sound generator as suggested by Boveja to a TMS apparatus as taught by Ruohonen in order to indicate proper placement of a TMS coil for subsequent treatment to a particular area of the cranium.

Allowable Subject Matter

9. Claims 10-15 and 38-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claims 10-15, the prior art of record does not teach or fairly suggest: a TMS system for providing treatment to a patient comprising: a TMS coil for treating the patient using a magnetic field; a pulse generating device that applies pulses to the coil during TMS treatment; a sensor disposed between the coil and a position at which pulses are applied, the sensor detecting proximity of the coil to the position; signal processing circuitry that processes output from the sensor to provide an indication of whether the coil is properly disposed with respect to the position receiving pulse therapy from the coil; wherein the sensor comprises at least one sensor disposed in or on a flexible substrate that is located between the coil and the position at which pulses are applied to determine if the coil is

properly positioned, wherein at least one sensor comprises membrane switches that change state when depressed, each switch comprising respective conductive films separated by a dielectric layer.

Regarding claims 38-41, the prior art of record does not teach or fairly suggest a device that detects proximity of a TMS coil to a position of a patient during TMS treatment using a magnetic field, comprising: a flexible substrate disposed between the coil and the position; at least one sensor disposed on the substrate in order to detect proximity of the coil to the position; wherein at least one sensor comprises membrane switches that change state when depressed, each switch comprising respective conductive films separated by a dielectric layer; wherein the conductive films have a sufficient resistance so as to reduce eddy currents.

Response to Arguments

10. Applicant's arguments filed 30 July 2009 with respect to the rejection of claims 1-7 and 59-66 under 35 U.S.C. 102(e) citing Ruohonen et al. ('040) have been fully considered and are not persuasive. Applicant contends that the sensors of Ruohonen are not disposed between the coil and a position at which pulses are applied. However, this argument is not persuasive. Ruohonen's sensors are indeed disposed between the coil and a position at which pulses are applied, as the sensor may be mounted on the shaft of eyeglasses, thus disposing the sensor between the coil and the patient's head (col. 5, lines 1-2). Furthermore, it is noted that the sensors are capable of being placed at a position between the coil and a position at which pulses are applied. Applicant

further contends that Ruohonen's fiducials are position sensors that detect a position in space, and therefore do not detect proximity of a coil to a position at which pulses are applied. However, this argument is not persuasive. The positional data can indeed show proximity of a coil to a particular position on the patient where the pulses are applied. The fiducials placed around the coil and the patient provide such positional information. In view of the foregoing, the rejection of claims 1-7 and 59-66 under 35 U.S.C. 102(e) citing Ruohonen et al. ('040) has been maintained.

11. Applicant's arguments filed 30 July 2009 with respect to the rejection of claim 36 under 35 U.S.C. 103(a) citing Boveja (U.S. Pub. No. 2001/0002441) have been fully considered and are not persuasive. Applicant contends that a feature indicated as allowable previously is now incorporated into the new claim 36, which should therefore place it in condition for allowance. However, this argument is not persuasive. The claim was indicated allowable for the claimed device as a whole, not just certain limitations within the claim language. Therefore, incorporation of specific claim language to claim 36 will not necessarily make the claim allowable. Furthermore, incorporation of the new limitation of "for treating a patient" does not distinguish the claim over Boveja, as Boveja discloses the therapeutic treatment of a patient [0028]. In view of the foregoing, the rejection of claim 36 under 35 U.S.C. 103(a) citing Boveja (U.S. Pub. No. 2001/0002441) has been maintained.

12. Applicant's arguments filed 30 July 2009 with respect to the rejection of claim 37 under 35 U.S.C. 103(a) citing Boveja (U.S. Pub. No. 2001/0002441) in view of Grove et al. (U.S. Pub. No. 2004/0167592) and claims 8 and 67 under 35 U.S.C. 103(a) as being unpatentable over Ruohonen et al. (U.S. Patent No. 6,849,040) in view of Boveja (U.S. Pub. No. 2001/0002441) and claims 9 and 68 under 35 U.S.C. 103(a) as being unpatentable over Ruohonen et al. (U.S. Patent No. 6,849,040) have been fully considered and are not persuasive. Applicant's arguments are contingent upon those presented with respect to claims 1 or 36 and since those have not been found persuasive for the reasons presented above, the rejection of claims 8, 9, 37, 67 and 68 has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. D. H./
Christine D Hopkins
Examiner
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